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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,814	02/27/2004	John G. Babish	068911-0075	5630

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
06/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/789,814	BABISH ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's response filed on 07/01/2009.

Currently, claims 4-7 are pending.

In view of new ground(s) of rejections, the finality made on 11/05/2008 is herein withdrawn, and the PROSECUTION IS HEREBY REOPENED.

The rejection of claims 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Applications No. 11/344552, 11/344554 is herein withdrawn. Note that applicant has filed terminal disclaimers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 03/035007, PTO-892).

Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one compound isolated or derived from hops. The compounds isolated or derived from hops include isoalpha acids, and reduced isoalpha acids which include isohumulone, isoprehumulone, dihydro-isohumulone, tetrahydroisohumulone. See abstract; page 7, TABLE 2; page 10, lines 6-10; page 11,

EXAMPLE 1; page 24, claims. The compositions therein can contain about 0.05 to about 1 wt % of compounds isolated or derived from hops. See page 8, lines 23-25.

Babish et al. does not expressly teach a method of treating inflammation comprising administering a combination of isohumulone, and dihydro-isohumulone, and the particular ratio of reduced isohumulone : dihydro-isohumulone as about 10:1 to about 1:10, in the composition.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ isohumulone, and dihydro-isohumulone in the method of treating inflammation because Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one compound isolated or derived from hops which include isohumulone, and dihydro-isohumulone. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e is to treat inflammation, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Babish et al., the instant claims contain two compounds used for treatment of inflammation. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 2004/037180, PTO-892).

Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one fraction isolated or derived from hops. The compounds in fractions isolated or derived from hops include isoalpha acids such as

isohumulone, isocohumulone, isoadhumulone, and reduced isoalpha acids such as dihydro-isohumulone, dihydro-isocohumulone, dihydro-isoadhumulone. See abstract; page 16; page 85, EXAMPLE 3; page 88, Table 4; pages 103-105; claims. The compositions therein can contain about 0.001 to about 10 wt % of compounds isolated or derived from hops. See page 47, lines 22-24.

Babish et al. does not expressly teach a method of treating inflammation comprising administering a combination of isoalpha acids, and reduced isoalpha acids, and the particular ratio of reduced isoalpha acids : isoalpha acids as about 10:1 to about 1:10, in the method therein.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a combination of reduced isoalpha acids, and isoalpha acids in the method of treating inflammation because Babish et al. teaches a method of treating inflammation comprising administering a composition comprising reduced isoalpha acids or isoalpha acids. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e is to treat inflammation, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Babish et al., the instant claims contain two compounds reduced isoalpha acids, and isoalpha acids used for treatment of inflammation. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91-92, 97-101, 105-106, 108-109 of copending Application 11/344555; over claims 51, 116, 118-130 of copending application 11/344557; as being unpatentable over claims of 35-36, 40, 43-46 of copending application 11/403034; as being unpatentable over claims 1, 39, 40-41 of 10/464,834; as being unpatentable over claims 250-256 of copending application 10/532,388; as being unpatentable over claims 52-53 of copending application 11/344,561; as being unpatentable over claims 1, 8, 13-14, 18-27, 152-153 of copending Application No. 10/464410; as being unpatentable over claims 1-2, 4, 6-7, 11-15 of copending application 10/789,817, in view of Kuhrts (US 2003/0091656, see page 3, paragraph [0024]). Although the conflicting claims are not identical, they are obvious over each other. The above copending applications claim administration of reduced isoalpha acids in treating inflammation. It would have been obvious to a person of ordinary skill in the art at the time of invention to employ isoalpha acids such as isohumulone, isocohumulone, isoadhumulone, in the method of treating inflammation because Kuhrts teaches that isohumulone, isocohumulone, isoadhumulone are useful in treating inflammation. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e treating inflammation., in order to form a composition which is used for the very same purpose i.e treating inflammation. The idea for combining them flows logically from their

having been used individually in the prior art. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpha acid : isoalpha acid, to obtain a desired effect such as reducing inflammation. One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the method of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

NOTE: Applicant has filed Terminal disclaimers to obviate the obviousness-type double patenting rejections over applications 11/344555, 11/344557, 11/403034, 10/464,834, 10/464,410, 10/789,817. The terminal disclaimers provided by the applicant have been disapproved by the office because attorney was not of record/POA required.

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 10/590,424. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims of 10/590,424. Note that, "A composition

comprising a fraction isolated or derived from hops" in the copending applications implies that the pharmaceutical composition would contain isoalpha and reduced isoalpha acid. The claimed composition is within the scope of the claims of the copending Application 10/590,424. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpha acid : isoalpha acid, to obtain a desired effect.

This is a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 4-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of 7,431,948, in view of Kuhrts (US 2003/0091656, see page 3, paragraph [0024]). Although the conflicting claims are not identical, they are obvious over each other. The US Patent 7,431,948 claims administration of reduced isoalpha acids in treating inflammation. It would have been obvious to a person of ordinary skill in the art at the time of invention to employ isoalpha acids such as isohumulone, isocohumulone, isoadhumulone, in the method of treating inflammation because Kuhrts teaches that isohumulone, isocohumulone, isoadhumulone are useful in treating inflammation. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e treating inflammation., in order to form a composition which is used for the very same purpose i.e treating inflammation. The idea for combining them flows logically from their having been used individually in the prior art. It would have

been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpha acid : isoalpha acid, to treat inflammation to obtain a desired effect such as reducing inflammation. One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the method of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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